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09/226,597	01/07/1999	JULIO PIMENTEL	585-017-84	9844

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-5 and 12-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 12-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed on July 14, 2006 is acknowledged and has been entered. Claims 1-5 have been amended. Claims 6-11 have been cancelled. Claims 12-41 have been added. Addition of claims 12-41 incorporates herein, a method of making the claimed composition. Accordingly, claims 1-5 and 12-41 are pending and are under examination.

Rejections Withdrawn

2. All rejections not reiterated herein have been withdrawn.

3. The rejections of claims 6 and 9-11 are now moot in light of Applicant's cancellation of the claims.

4. In light of Applicant's amendment, the rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, as not being enabled, is hereby, withdrawn.

5. In light of Applicant's amendment, the rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 12-17, 23, and 35-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 preamble is indefinite in failing to recite what is intended purpose for the claimed method steps provided in the body of the claim, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 1 is vague and indefinite in reciting, "feeding an animal food and ... anti-lipase antibody" because it is unclear as to whether the food and the anti-lipase antibody are in a formed mixture of food; or are the two elements intended to be fed to the animal separately, as recited.

Claim 3 is confusing in relation to claim 1 from which it depends because claim 1 appears to recite a "method of using [a composition]" claim such as for feeding an animal, whereas the instant claim recites "storing" the composition in a particular state, i.e. wet state or freeze dried, which appears to be encompassed in a "method of forming" claim. Accordingly, it is unclear what structural and functional cooperative relationship exists between the elements of the instant claim and those of claim 1 from which it depends.

Claim 12 is also confusing in relation to claim 1 from which it depends. Same analogous comments and problems in claim 3 apply to claim 12.

Claim 17 lacks clear antecedent basis problem in reciting, "said liposome-encapsulated avian anti-lipase antibody".

Claim 23 is objected to as being a duplicate of claim 18.

Claim 35 is indefinite in reciting, "new" because the term "new" is a subjective term that lacks a comparative basis for defining its metes and bounds in relation to the set of claims.

Claim 35 is indefinite in reciting, "a solution" in step 1 of the claim and "a new solution" in step 2 of the claim because a same term "solution" is used to reference two different elements in the claim; hence, rendering the claim confusing. Perhaps Applicant intends, "the resulting mixture" or similar language, instead of "a new solution" to refer to the second occurrence of the term "solution".

Claim 36 is also indefinite as in claim 35 from which it depends in reciting, "a new solution". Same analogous comments and problems in claim 35 apply to claim 36.

Claim 37 is also indefinite as in claim 35 from which it depends in reciting, "a new solution". Same analogous comments and problems in claim 37 apply to claim 35.

Claim 38 is indefinite in reciting, "new" because the term "new" is a subjective term that lacks a comparative basis for defining its metes and bounds in relation to the set of claims.

Claim 38 is indefinite in reciting, "a solution" in step 1 of the claim and "a new solution" in step 2 of the claim because a same term "solution" is used to reference two different elements in the claim; hence, rendering the claim confusing. Perhaps Applicant intends, "the resulting mixture" or similar language, instead of "a new solution" to refer to the second occurrence of the term "solution".

Claim 39 is also indefinite as in claim 38 from which it depends in reciting, "a new solution". Same analogous comments and problems in claim 38 apply to claim 39.

Claim 40 is also indefinite as in claim 1 from which it depends in reciting, "a new solution". Same analogous comments and problems in claim 38 apply to claim 40.

Claim 41 is confusing in relation to claim 38 from which it depends because claim 38 appears to recites a "composition formed by a process" claim, whereas the instant claim recites "feeding said composition to an animal", which appears to be encompassed in a "method of using" claim. Accordingly, it is unclear what structural and functional cooperative relationship exists between the elements of the instant claim and those of claim 38 from which it depends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-5 and 12-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US Patent 5,919,451) in view of Drent et al. (Lipase inhibition: a novel concept in the treatment of obesity, International Journal of Obesity 17: 241-244 (1993)) and in further view of LeClercq et al. (Metabolism of very low density lipoproteins in genetically lean or fat lines of chicken, Reproduction, Nutrition, Development, 30 (6): 701-715 (1990)).

Cook et al. provide a method for improving the growth of an animal and improving efficiency of the animal to convert its feed into desirable lean body tissue. Cook et al. specifically disclose feeding to the animal a food composition comprising a liposome-encapsulated immunoglobulin or antibody that helps protect the animal from disease and/or antigens that can affect the animal's growth and physiology (see column 1, lines 18-23 and column 2, lines 1- 6). The antibodies used in this invention are those that can alter physiological processes that adversely affect growth and feed efficiency or they can be antibodies that provide protection against diseases or against specific endogenous regulators of food intake or gastrointestinal mobility, i.e. lipase (see column 3, lines 5-14). The food composition is made by forming a nutrient mixture and then depositing the liposome-encapsulated antibody into the pellet core (see column 2, lines 12-21). The antibodies may be provided in solution, in an aqueous or lipid carrier, i.e. liposome-encapsulation, and may also be directly applied to the pellet core without a carrier (freeze-dried) such as a powder. The antibodies are, however, preferably

encapsulated in liposome. The antibodies are avian, i.e. obtained from egg of a hen which has been injected with antigen that results to the production of its corresponding antibodies (see column 2, lines 22-46). The food protein and carbohydrate may also include vitamins and dietary lipid (column 2, lines 54-67 and column 4, lines 1-19). Specifically, the food composition containing the avian antibodies is fed to the animals in an amount effective to passively immunize the animal or otherwise enhance the efficiency of feed conversion by the animal (column 1, lines 41-52 and column 3, lines 1-4). Cook et al.'s food composition and method are prepared as animal feed for use in either mammals (pets), or avians such as ducks, chickens, and turkeys (see column 6).

Cook et al. differ from the claimed invention in failing to teach that the antibodies are anti-lipase antibodies, or antibodies directed against lipase antigen.

Drent et al. teach that lipase inhibition is a novel concept in the treatment of obesity. Specifically, Drent et al. teach that by inhibiting gastric and pancreatic lipase, absorption of dietary fat is reduced due to inhibition of triglyceride hydrolysis. Drent et al. tested and confirmed the concept using oral administration of the compound, Orlistat, which is an inhibitor of gastric, carboxylester and pancreatic lipase and which has served useful in weight reduction in humans because of its inhibitional effect on gastrointestinal lipases (see Abstract, page 241 and page 243, column 2).

Leclercq et al. teach using anti-lipoprotein lipase antibodies to completely inhibit lipoprotein lipase in fat lines and lean lines of chickens (see page 703, column 2 to page 704, column 1). At page 705, column 2 to page 706 and page 709, column 2 to page

711, LeClercq confirmed that anti-lipoprotein antibodies are able to inhibit lipoprotein lipase activity, and conclude that difference in fatness is not due to difference in feed intake but to metabolic deviations depending on hormonal control.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Drent of oral administration of Orlistat as modified by the teaching of LeClercq of the similar effect by anti-lipase antibodies as Orlistat, into the method as taught by Cook of feeding to animals antibodies that are incorporated into food composition, that are directed against antigen inhibitors and regulators of metabolism in order to effect inhibition or regulation of that particular antigen in the animal because anti-lipase antibodies as taught by LeClercq is seen to effect inhibition of lipase activity as does Drent in teaching use of Orlistat to inhibit same for purposes of weight loss.

Cook et al., LeClercq et al., and Drent et al. do not disclose that the composition contains 25 to 1000 mg of liposome encapsulated anti-lipase antibodies per kilogram of the animal food, as recited in claims 14, 15, 17, and 22.

Cook et al. specifically disclose administering a safe and effective amount of antibody that would help protect the animal from disease or other antigens that can adversely affect animal's growth or the efficiency of the animal to convert feed into desirable body tissue. Therefore, the amount of liposome-encapsulated anti-lipase antibody contained in a food composition should be a safe and effective quantity.

Such ranges of antibody concentrations in food composition, are rendered as result effective variables, which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233,235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215,218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in claims 14, 15, 17, and 22 are for any particular purpose or solve any stated problem and the prior art teaches that effective concentrations of antibodies or compounds used may vary according to the animals being fed and/or their characteristics, absent unexpected results, it would have been obvious for one of ordinary skill to discover the safe and effective amounts of antibodies and compounds used for the composition and method disclosed by the prior art by normal optimization procedures.

Response to Arguments

8. Applicant's amendment filed July 14, 2006 necessitated the new grounds of rejection presented in this Office Action. Submission of the amendment was not

accompanied by arguments to prior Office Action rejections, as Applicant's amendment mooted the written description and enablement rejections.

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
September 21, 2006